

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

**THE BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS SYSTEM,**

Plaintiff,

V.

Civil Action No. 4:16-cv-03155

NANTHEALTH, INC.;
NANTWORKS, LLC;
NANT HOLDINGS IP, LLC;
And DR. PATRICK SOON-SHIONG,

Defendants.

DECLARATION OF PATRICK SOON-SHIONG, M.D.

I, Dr. Patrick Soon-Shiong, declare under penalty of perjury under the laws of the United States that the following is true and correct.

1. I am submitting this declaration in support of Defendants' Motion to Dismiss for Lack of Personal Jurisdiction or, In the Alternative, To Transfer. I have personal knowledge of the following facts and am competent to testify thereto.

Education and Professional Background

2. I graduated in 1975 as an MD fourth in my class of 200 from the University of Witwatersrand, Johannesburg, South Africa at the age of 23 and completed a master's degree in science four years later at the University of British Columbia, Vancouver, Canada. By the age of 31 I had completed my fellowship as a board-certified surgeon in Canada and I then received board certification from the American College of Surgeons in 1996.

3. I am a trained physician, surgeon and scientist. Over the course of my career, I

have pioneered novel therapies for both diabetes and cancer, published over 100 scientific papers, abstracts and book chapters, and am a named inventor on over 230 issued United States and international patents spanning myriad fields including medicine, artificial intelligence, and technology. In the early 1990s, I pursued the science of stem cell and nanotechnology at NASA, performing experiments as part of the Shuttle program. My path to cancer research began while conducting research for NASA that involved harnessing stem cells to make insulin. In 1991, I founded a biotechnology company to develop a novel nanoparticle anticancer drug with the concept of using “the tumor’s biology against itself.” From 1997 to 2010, I served as Founder, Chairman and Chief Executive Officer of two global pharmaceutical companies, American Pharmaceutical Partners and Abraxis BioScience. I invented and developed Abraxane, a drug approved by the Food and Drug Administration (“FDA”) for metastatic breast cancer in 2005, lung cancer in 2012, and pancreatic cancer in 2013. I am involved in a variety of philanthropic efforts, including serving as the Chairman of the Chan Soon-Shiong Family Foundation and of the Chan Soon-Shiong Institute of Molecular Medicine, a non-profit medical research organization. I recently gave \$135 Million to Saint John's Health Center to build a biotech research center and sports medicine clinic and underwrote \$100 Million to help reopen the Martin Luther King Jr. Hospital to serve an otherwise underserved community without access to adequate health care. My wife and I have signed the Giving Pledge, an initiative launched by Warren Buffett and Bill Gates, through which we have committed to giving the majority of our wealth to philanthropic causes and charitable organizations.

4. My current positions include:
 - a. Chairman & CEO – NantWorks, LLC
 - b. Chairman & CEO – NantHealth, Inc.

- c. Chairman & CEO – NantKwest, Inc.
 - d. Founder & Chairman – Chan Soon-Shiong Family Foundation
 - e. Executive Director – Wireless Health Institute (WHI) UCLA
 - f. Adjunct Professor of Surgery at UCLA
 - g. Visiting Professor of Imperial College of London
 - h. Professor of Microbiology, Immunology & Molecular Genetics and
Professor of Bioengineering at the California NanoSystems Institute of UCLA
5. My former positions include:
- a. Founder, Chairman and CEO – American Pharmaceutical Partners (APP)
 - b. Founder, Chairman and CEO – Abraxis BioScience
 - c. Global Advisory Board – Bank of America
 - d. Co-chair of the CEO Council for Health and Innovation at the Bipartisan
Policy Center
6. Selected awards and honors include:
- a. Eisenhower Medical Center, Peter Kiewit Distinguished Membership in
Medicine (1994)
 - b. Gilda's Club New York City, Award for the Advancement of Cancer
Medicine (2006)
 - c. Caritas Gala Award Honoree (2007)
 - d. Ellis Island Medal of Honor Award Recipient (2007)
 - e. USC Viterbi School of Engineering, Daniel J. Epstein Engineering
Management Award (2008)
 - f. Martin Luther King Jr. Labor Breakfast Tribute: LA County Federation of

Labor, L.A. Union (2010)

- g. Friends of the National Library of Medicine: 2010 Distinguished Medical Science Award (2010)
- h. City of Hope – 2012 Honorary Degree Recipient (2012)
- i. UCLA Medical Center Visionary Ball, “Medical Visionary Award” (2013)

7. Most recently, April 2016, I received the Franklin Institute Award for visionary leadership and commitment to advancing medical and scientific research and bringing new treatment options to cancer patients. I was also honored at the Vatican in April 2016 and received the 2016 Pontifical Key Visionary Award. The award recognizes “medical innovators who change the course of history and reduce suffering on a global scale by blending visionary thinking with real action.”

Original Scientific Contributions

8. Since the late 1980s, I pursued the science of transplantation, protein-protein interaction, stem cell and nanotechnology at UCLA and NASA, performing experiments as part of the Shuttle program (STS-80). My path to cancer research began while conducting research for NASA that involved harnessing the stem cells to make insulin.

9. My original scientific contributions, outlined below in scientific publications as well as scientific meetings, span the field of biology, immunology and biological mechanisms of cancer as follows:

- a. **Pancreas Physiology in Man (1987): Elucidation of Enzymatic Pancreatic Function in Man.** In 1982, together with Dr. Swafford we performed the nation’s first whole organ auto transplant of the pancreas in

a patient with pancreatitis. This successful operation enabled the study of how insulin and pancreatic enzymes are secreted in response to glucose in the absence of any nerve connections:

- i. Soon-Shiong P, Swafford G, Levin S: Successful long-term exocrine and endocrine function in the auto transplanted pancreas in man. *Pancreas* 2(3): 357-61, 1987;
- b. **Original Discovery of Monoclonal Antibody Purification of Pancreatic Islet Cell (1988-1991).** In 1985-1990, we identified immunological methods and novel antibodies present in human pancreatic cells:
 - i. Soon-Shiong P, Heintz R, Terasaki P: An immunological method of islet cell purification using cytotoxic anti-acinar cell monoclonal antibodies. *Transplant Proc* 20 (suppl 1):61-63, 1988;
 - ii. Soon-Shiong P, Heintz R, Terasaki P: Characterization of monoclonal antibodies CBL3 and TT62 with differing antigenic determinants specific for isolated human islet cells. *Biochem Biophys Res Comm* 150(2): 775-80, 1988;
 - iii. Soon-Shiong P, Heintz R, Terasaki P: Identification of novel blood group-reactive monoclonal antibodies cytotoxic to human acinar cells but not islets. *Transplant Proc* 21(1 Pt 3): 2622-3, 1989; and
 - iv. Soon-Shiong P, Terasaki P, Lanza RP: Immunocytochemical identification of monoclonal antibodies with binding activity to acinar cells but not islets. *Pancreas* 6(3): 318-23, 1991;
- c. **Original Development of Microencapsulation Technology &**

Discoverer of Immunological Responses to Alginate (1991). From 1985 to 1995, we developed unique delivery systems involving sugars (polysaccharides) and proteins for the treatment of life threatening diseases such as diabetes and liver failure in cancer. From scientific concept in the late 1980s to translation into man in the form of clinical trials, was accomplished in less than ten years:

- i. Soon-Shiong P, Otterlie M, Skjak-Braek G, Smidsrod O, Heintz R, Lanza RP, Espevik T: An immunological basis for the fibrotic reaction to implanted microcapsules. Transplant Proc 23(1 Pt 1):758-9, 1991;
- ii. Sawhney A, Soon-Shiong P, Hubbell J: Biocompatible microcapsules for in vivo transplantation of animal tissue. Trans Soc for Biomaterials 14, 1991;
- iii. Soon-Shiong P, Heintz R, Merideth N, Feldman E, Nelson R, Skjak-Braek G, Smidsrod O, Espevik T, Otterlei M: Successful reversal of Type I diabetes by a bioartificial pancreas. Diabetes 40(1):295A, 1991; and
- iv. Otterlei, Ostgaard K, Skjak-Braek G, Smidsrod O, Soon-Shiong P, Espevik T: Induction of cytokine production from human monocytes stimulated with alginate. J Immunother 10: 286-91, 1991;
- d. **Early Demonstration of Role of Natural Killer Cells (1990).** Demonstration of the efficacy of specific cytotoxicity by cytotoxic T-

lymphocyte (CTL) and nonspecific killing by Natural Killer (NK) cells against pancreatic tumor cells. This work in 1990, has formed the basis of Cancer MoonShot 2020 in which the realization that Natural Killer cells are involved in the innate protection of man against cancer. We pursued this concept and by 2015, have demonstrated safety and efficacy in patients with multiple myeloma, non-Hodgkin lymphoma, acute myeloid leukemia and solid tumors. To our knowledge, none of this clinical trials or basic research in natural killer cells as a MoonShot program has been performed at MD Anderson to date. Furthermore, by 2015 we raised funds to build manufacturing plants and since demonstrated complete responses of Natural Killer cell activity in patients with Merkel Cell Melanoma.

This concept of “Off-the-shelf Natural Killer cell” platform was conceived since 1992 and launched into clinical trials over a decade ago and is key to Cancer MoonShot 2020, where activated natural killer cells (NK-92) have completed Phase I trials and is now in mid-stage to late-stage trials across the nation. There are no such trials using our off-the-shelf NK-92 cells present at MD Anderson where they state in a recent 2015 post:

*“If natural killer cells can be obtained and prepared efficiently, then natural killer cell therapy could become readily available to cancer patients. One of the **upcoming** solid tumor studies will test whether natural killer cells **can feasibly be generated** from blood bank products as an off-the-shelf product to be stored frozen and ready to thaw and infuse into patients.”*

Thus in comparison to this statement above, the off-the-shelf Natural Killer cell element of our Cancer MoonShot 2020 program is significantly

more advanced in the clinic when compared to any program at MD Anderson and began as early as 1990. The NK Cancer MoonShot 2020 began from the concept of the role of Natural Killer cells in 1990 (publication below), to the discovery of off-the-shelf NK-92 in 1992 at the University of British Columbia by Dr. Hans Klingemann, to the founding and launch of NantKwest as a public company, (2015) and has now reached the stage of large-scale manufacturing capacity for all cancer types.

- i. P Soon-Shiong, Z.-N. Lu, I. Grewal, R. Lanza and W. Clark
Molecular Biology Institute, University of California, USA
Departments of Medicine and Surgery, University of California
Medical Center, and Surgical and Research Services, VA
Wadsworth Medical Center, Los Angeles, California, USA:
Prevention of CTLA and NK Cell-Mediated Cytotoxicity by
Microencapsulation;

e. **World's First Reversal of Type I Diabetes in Diabetic Dogs Using
Micro-Encapsulated Insulin Producing Cells (1992-1994):**

- i. Soon-Shiong P, Feldman E, Nelson R, Komtebedde J, Smidsrod O,
Skjak-Braek G, Espevik T, Heintz R, Lee M: Successful reversal
of spontaneous diabetes in dogs by intraperitoneal
microencapsulated islets. Transplantation 54: 769-74, 1992;
- ii. Soon-Shiong P, Reversing Diabetes, R&D Directions 12-16,
December 1995;

- iii. Soon-Shiong P, Sandford P: Encapsulated islet cell therapy for the treatment of diabetes: intraperitoneal injection of islets. Surgical Technology International IV:93-95, 1995;
- iv. Soon-Shiong, P. Encapsulated islet transplantation: Pathway to human clinical trials. Pancreatic Islet Transplantation III 81-92, 1994; and
- v. Soon-Shiong P, Feldman E, Nelson R, Heintz R, Yao Q, Yao Z, Zheng T, Merideth N, Skjak-Braek G, Espevik T, Smidsrod O, Sandford P: Long-term reversal of diabetes by injection of immunoprotected islet cells. Proc Natl Acad Sci 90(12): 5843-7, 1993;
- f. **World's First Reversal of Type I Diabetes in Patients Using Micro-Encapsulated Insulin Producing Allogenic & Stem Cells (1993-1995).**
Our demonstrated ability to translate from basic scientific concept (1991), see 'paragraph c' above to clinical trials (1993) of a revolutionary delivery system in man for the treatment of a life-threatening disease is evident by the experience below. This ability to rapidly translate scientific insight into clinical applications is the core to Cancer MoonShot 2020 where the goal is to reduce the time of application of combination immunotherapy, natural killer cell therapy, and vaccine therapy from ten years to five:
- i. **Whole Organ Pancreas Transplant: Allograft Whole Organ (1986-1988) – (Exhibit 1):**
 - 1. Dec 5, 1986 – I performed California's first pancreas whole

organ pancreas transplant in a type I diabetic patient at UCLA; and

2. January 24, 1988 – I performed California’s first combined kidney pancreas transplant in a type I diabetic patient at UCLA;

ii. **Microencapsulated Pancreas Transplant: Allograft Islet Cell (1993-1994):**

1. May 14, 1993 – I performed the world’s first microencapsulated artificial islet cell transplant in a type I diabetic and published the data in 1994 below: (Exhibit 2)
 - a. Soon-Shiong P, Heintz R, Merideth N, Yao Qiang X, Yao Z, Zheng T, Murphy M, Moloney M, Schmehl M, Harris M, Mendez R, Sandford P: Insulin independence in a Type I diabetic patient after encapsulated islet transplantation. Lancet 343(8903): 950-1, 1994

iii. **Microencapsulated Pancreas Transplant: Allograft Adult Islet Stem Cell (1995):**

1. By 1995, I performed the nation’s first encapsulated islet cell stem cell transplant. The results were presented by the Juvenile Diabetes Foundation of 25 years’ progress in Diabetes. (Exhibit 3)

iv. **Microencapsulated Xenotransplant: Xenograft Pig to Man**

Islet Cell Transplant (1998):

1. In 1998 I performed the world's first alginate based micro-encapsulated pig to man islet cell transplant at the University of Auckland New Zealand and my collaborator, Professor Elliott presented data at the 1st International Conference on Clinical Islet Xenotransplantation in Osaka, Japan. (Exhibit 4)

- g. **Evolution of Cancer Chemotherapy Delivery & Low-Dose Metronomic Chemotherapy (1997 – 2016).** In the early 1990s, we invented the first human protein nanoparticle to deliver chemotherapy at a higher concentration and a lower dose to the tumor microenvironment. Again, we demonstrated the capability to execute from concept (ABI-007 Protein Nanoparticle) to clinical trial to FDA approval (Abraxane) in a span of a decade. The goal of Cancer MoonShot 2020 is to reduce this time from a decade to three to five years such that a cancer vaccine is approved by the year 2020. This differs significantly from multiple “moonshots” at multiple programs.

- i. **World's First Invention of the Human Protein Nanoparticle Delivery System to Accomplish Transcytosis to the Tumor Microenvironment (1997-2016):**

1. Desai NP, Tao C, Magdassi SM, Ci S, Yang A, Louie L, Valente G, Yao Z, Zheng T, Sandford P, Spaulding G, Soon-Shiong P: Protein-stabilized nanoparticles as drug

delivery vehicles. 23rd Annual Meeting of the Society for Biomaterials, 4/30-5/4, 1997, New Orleans, Louisiana, USA; and

2. Since this initial publication, I have received allowance and published over 149 patents (46 in the United States and 103 foreign) patents covering this nanoparticle technology demonstrating its effectiveness to transcend the endothelial cell barrier and allow delivery of low dose chemotherapy to the tumor microenvironment to enable activation of the body's immune system for tumor killing. (Exhibit 5)

ii. **FDA & Global Approval of Abraxane, the World's First Albumin Based Nanoparticle of Paclitaxel for Breast Cancer, Lung Cancer, and Pancreatic Cancer (2005-2014) – Exhibit 6:**

1. Ibrahim NK, Desai N, Legha S, Soon-Shiong P, Theriault RL, Rivera E, Esmaeli B, Ring SE, Bedikian A, Hortobagyi GN, Ellerhorst JA. Phase I and pharmacokinetic study of ABI-007, a Cremophor-free, protein-stabilized, nanoparticle formulation of paclitaxel. Clin Cancer Res. 8(5):1038-44, 2002;
2. Intraarterial Chemotherapy with Polyoxyethylated Castor Oil Free Paclitaxel, Incorporated in Albumin Nanoparticles (ABI-007);
3. Nanoparticle Paclitaxel Formulation Shows Dose Response

in Phase II Trials;

4. Nanoparticle Paclitaxel Doubles Response Rate; and

5. FDA Approves New Drug, Abraxane, for Treatment of Advanced Breast Cancer;

iii. **Demonstration of Transcytosis and Rapid Absorption by Tumor Tissue Through Gp60 Receptor and Role of Low-Dose Metronomic Chemotherapy – Exhibit 7**

1. Nanoparticle Paclitaxel Doubles Response Rate;

2. Drawing a Bead on Side Effects: Drugmakers are figuring out ways to make some old remedies safer;

3. Ng SS, Sparreboom A, Shaked Y, Lee C, Man S, Desai N, Soon-Shiong P, Figg WD, Kerbel RS. Influence of formulation vehicle on metronomic taxane chemotherapy: albumin-bound versus cremophor EL-based paclitaxel. Clin Cancer Res. 12(14 Pt 1):4331-8, 2006; and

4. Gemcitabine Plus nab-Paclitaxel is an Active Regimen in Patients with Advanced Pancreatic Cancer: A Phase I/II Trial;

iv. **Demonstration that Abraxane is Effective in Metastatic Pancreatic Cancer at Metronomic Low Doses and Activation of the Immune System Can Achieve Sustainable Long Term Remission in Patients with End-Stage Pancreatic Cancer – Exhibit 8**

1. Ng SS, Sparreboom A, Shaked Y, Lee C, Man S, Desai N, Soon-Shiong P, Figg WD, Kerbel RS. Influence of formulation vehicle on metronomic taxane chemotherapy: albumin-bound versus cremophor EL-based paclitaxel. Clin Cancer Res. 12(14 Pt 1):4331-8, 2006;
2. Gemcitabine Plus nab-Paclitaxel is an Active Regimen in Patients with Advanced Pancreatic Cancer: A Phase I/II Trial;
3. 60 Minutes CBS Story on Dr. Patrick Soon-Shiong;
4. David R. Pancreatic Cancer Patient; and
5. Diane R. Pancreatic Cancer Patient.

History of the “Rocketship” Concept

10. Formation of the “Rocketship” (2005-Current) (Exhibit 9, Page 1).

- a. Since 1995, I had the firm belief that integration and collaboration was needed to advance science and translational medicine in the field of cancer, diabetes, and life threatening diseases. I was invited to present these views by the director of the National Institutes of Health (Natcher Conference Center), (Exhibit 9, Page 2) at the Biomaterials and Medical Implant Science: Present and Future Perspectives. A National Institutes of Health Workshop. October 16-17, 1995. At that conference, I stated that “breakthrough therapies involving biomaterials delivered through minimally invasive techniques will revolutionize the treatment of life-threatening diseases for which no effective therapy currently exists.” I noted further that “the promise of such therapy is evidenced by the

successful reversals of Type 1 diabetes in patients by a simple injection of self-regulating, insulin-secreting cells that are protected by a semipermeable biomaterial membrane. *Next-generation therapeutic delivery systems will allow interaction with the biological milieu and provide new therapies through specific targeting of therapeutic agents to diseased organs, through non-viral delivery of gene products, and through self-regulated release of hormones or peptides. The implications for health care in the United States, for patients afflicted with chronic debilitating diseases, for the scientific community, and for the U.S. economy are enormous. To realize the full potential of these biological interactive systems, it is imperative that a multidisciplinary infrastructure be established to allow the full integration of scientists working in fields as diverse as clinical medicine, surgery, biomaterial science, and cellular and molecular biology. Such institutions will be the pharmaceutical production sites of the future and will facilitate the rapid transition of discoveries from the laboratory bench to proof-of-principle in man as safely and efficiently as possible.*”

- b. This insight formed the basis of the build out of the Rocketship leading to Cancer MoonShot 2020. It is this Rocketship together with a detailed briefing document that was provided to Dr. Lynda Chin on multiple occasions, including a visit by Dr. Ronald DePinho and Dr. Lynda Chin*
- c. IOM Report (2009) (Exhibit 9, Page 8). To pursue the Rocketship concept, I established the non for profit, Institute of Advance Health and

sponsored a meeting at the Institute of Medicine in Washington DC to present the scientific basis for the nation to pursue grid computing, interoperability, and a clinical learning system for healthcare transformation. The concept was termed the “Rocketship” (Exhibit 9, Page 1). The agenda, attendees, and draft report of the discussions are attached (Exhibit 9, Pages 8-18).

- d. Since 2009, we have built the infrastructure of the Rocketship including a national layer one fiber enabling the transfer of genomic data at terabyte speeds, a supercomputer enabling bioinformatics machine learning artificial intelligence to deduce mutations at speeds of less than 60 seconds per patient enabling clinical utility of cancer genome data. This Rocketship formed the basis of Cancer MoonShot 2020 program which was launched in 2015 and publicly announced in 2016.
- e. Details of the Cancer MoonShot 2020 program was provided in a briefing document to President Clinton in January 2014 (Exhibit 10) and the document was shared with Dr. Lynda Chin (Email Exhibit 11) in January 2014. At that time, Dr. DePinho and Dr. Lynda Chin was invited to participate in the Omics Network and Genomics America as outlined in the briefing document (Exhibit 10).

11. Scientific and clinical disagreement with MD Anderson regarding high dose chemotherapy vs. low dose metronomic use (1998-Present)

- a. Around 1998, I initiated a Phase I clinical trial of our nanoparticle (ABI-007) at MD Anderson. The dose extended to 360mg per meter² and the

study showed that at that dose, the drug significantly reduced the patient's white cells and hence impaired the immune system. The results of the Phase I trial were published in 2002: Ibrahim NK, Desai N, Legha S, Soon-Shiong P, Theriault RL, Rivera E, Esmaeli B, Ring SE, Bedikian A, Hortobagyi GN, Ellerhorst JA. Phase I and pharmacokinetic study of ABI-007, a Cremophor-free, protein-stabilized, nanoparticle formulation of paclitaxel. Clin Cancer Res. 8(5):1038-44, 2002

- b. On the basis of this data, I requested that our Phase II trial should proceed with a low, metronomic weekly dose, but MD Anderson refused, demanding instead that a dose three times higher ($300\text{mg}/\text{m}^2$) every three weeks) be the mid-stage trial dose for breast cancer. My concern was at this dose the patient's white cells would be obliterated and the immune system would be impaired, inducing unnecessary toxicities with poorer outcomes. I was given an ultimatum that unless I agreed to the higher dose, MD Anderson would not pursue the trial. On that basis, I chose to leave MD Anderson and instead performed the trial at a lower dose at Northwestern University.
- c. By 2000, we performed at the Istituto Nazionale Tumori, Milano Italy clinical trials of ABI-007 in patients Squamous Cell Carcinoma of the head and neck demonstrating an 80.9% complete and partial response with a recommended Phase II dose of $230\text{mg}/\text{m}^2$, validating my desire to pursue lower dose chemotherapy. This data was published in 2001:
 - i. Intraarterial Chemotherapy with Polyoxyethylated Castor Oil Free

Paclitaxel, Incorporated in Albumin Nanoparticles (ABI-007)

- d. By 2006, we clearly demonstrated the advantage of metronomic low dose Abraxane therapy and instituted this protocol in patients with metastatic pancreatic cancer.
 - i. Ng SS, Sparreboom A, Shaked Y, Lee C, Man S, Desai N, Soon-Shiong P, Figg WD, Kerbel RS. Influence of formulation vehicle on metronomic taxane chemotherapy: albumin-bound versus cremophor EL-based paclitaxel. Clin Cancer Res. 12(14 Pt 1):4331-8, 2006;
 - ii. David R. Pancreatic Cancer Patient (Exhibit 8); and
 - iii. Diane R. Pancreatic Cancer Patient (Exhibit 8);
- e. By 2014, after multiple visits between ourselves and Dr. DePinho and Dr. Lynda Chin, the sharing of the briefing document (Exhibit 11) it was clear that this scientific and clinical disagreement regarding the immunotherapy approach to treating cancer patients persisted between ourselves and leadership (Dr. DePinho and his wife Dr. Chin). On that basis, we made the decision not to fund Dr. DePinho and Dr. Lynda Chin since our concern that instituting high-dose chemotherapy is contrary to the concept of preserving the immune system and contrary to the core principles of Cancer MoonShot 2020. Based on this decision that Dr. DePinho and Dr. Chin's vision of cancer therapy was inconsistent with Cancer MoonShot 2020, they were not invited guests to the working group session of the Omics Network held in New York on December 3, 2014. The issues

being addressed by the working group included:

- i. Formation of The National Cancer Provider Health Network
- ii. Participation of the Self-Insured and Payers
- iii. Defining the Hereditary Basis of Cancer, Chronic Diseases and Childhood Disease
- iv. Pharma Addressing the Challenge of Heterogeneity of Cancer
- v. Global Collaborative

Attendees included members across this entire ecosystem from both national and international bodies. The assertion by Dr. DePinho and Dr. Chin that we usurped their moon shot program is baseless when the agenda provided clearly demonstrates a program unique to Cancer MoonShot 2020.

12. **Health Transformation Institute (HTI)** formation to implement Rocketship (2009). In collaboration with the University of Arizona, President Michael Crow, we established the Healthcare Transformation Institute to further the concept of the “Rocketship” as an aspiration to transform healthcare-the beginnings of the “moonshot”. The term “Rocketship” was coined based on, among other things, our background work with NASA and artificial intelligence needed to transform healthcare, cancer care, and life threatening diseases such as diabetes. There was also collaboration with National Institute of Clinical Excellence (NICE) in the United Kingdom to pursue the “Rocketship.” (*See Exhibit 13*).

Background on the Creation of the Naming and Trademark “Cancer MoonShot 2020”

Program

13. This case involves the name of the Cancer MoonShot 2020 program, one of the most comprehensive, collaborative initiatives launched to date seeking to accelerate the potential of combination immunotherapy as the next generation standard of care in cancer patients. The program initiative aims to explore a new paradigm in cancer care by initiating trials involving 20 tumor types in 20,000 patients by 2020. These findings will inform additional trials and the aspirational “moonshot” to develop an effective vaccine-based immunotherapy to combat cancer by 2020.

14. The Cancer MoonShot 2020 program invites collaboration across pharma, community and academic oncology, government, and scientific communities. This joint approach would provide researchers with necessary testing materials and patients with more opportunities to participate through local facilities and wider insurance coverage.

15. Ultimately, the aim of the moonshot is to win the war on cancer -- to reach a point in five years where we manage cancer the same way we might manage any chronic disease, such as diabetes or asthma. The goal is to reduce the time from a decade to five years when we can finally stop the practice of administering toxic therapies, such as high-dose chemotherapy and high-dose radiation that decimate the immune system, and instead transform cancer care by harnessing the full power of our own innate protective immune system we are born with, the guardian cell called the Natural Killer cell. By activating the body’s natural killer cells to fight off the cancer the way they were designed to do and by supplementing with off-the-shelf NK cells, we strive to end cancer as we know it by the year 2020 across all tumor types and at all stages. This program is distinct from Dr. DePinho and Dr. Lynda Chin’s pursuit of high dose

chemotherapy and checkpoint inhibitors. The goal of Cancer MoonShot 2020 is definitive with a timeline and timeframe (within the next four years) when the science of natural killer cells is validated and patients are not only surviving the diagnosis, but living – even thriving – with cancer.

Introduction of Cancer MoonShot 2020 to the US Government

16. My ideas for a cancer moonshot are what informed Vice President Joe Biden and his plans for a Government-backed moonshot program. The fight against cancer is a non-partisan issue. Indeed, in addition to encouraging the current administration, I recently met with President-Elect Donald Trump to encourage his administration to continue the fight against cancer by establishing a national and global collaborative in which our innate protective system could be harnessed and change the course of this disease forever.

17. My discussions with the current administration regarding the fight against cancer began in 2015, when Vice President Biden contacted me around April 2015 seeking advice with regard to his son's brain cancer and a request to interact with the treating physicians at MD Anderson. Over the course of multiple personal interactions with Vice President Biden, he became acutely aware of the paradigm change in cancer care and our natural killer cell and vaccine approach, as well our cutting-edge development known as "Whole Genomic Sequencing and Proteomics" to better inform treatment of patients suffering from cancer. This form of analysis was not present at MD Anderson in 2015 and is still not available as a clinical CLIA-CAP Certified test. It is this test that is a core of the Cancer MoonShot 2020 program and hence completely differentiated from any "moonshot" program currently in motion at MD Anderson.

18. On October 6, 2015, I met with Vice President Biden at the White House. Exhibit 12 is comprised of photographs from the White House meeting. In preparation for this meeting,

I wrote a white paper with input from the Genomics America coalition, titled “**The Precision Against Cancer PAC: The Moonshot Program to Develop a Cancer Vaccine for ‘I am N = 1’**” with the concept of a vaccine-based immunotherapy and the Cancer MoonShot 2020 initiative. *See* Exhibit 14. I provided Vice President Biden and his advisors with a copy of this white paper during our October 6 meeting. I began the paper by explaining that, “**In the way that JFK took us to the moon, this Administration has the opportunity to complete its own moonshot moment.**” I went on to describe how, with the advent of next-generation genomic sequencing and precision immunotherapies, there is the possibility of creating patient-specific cancer vaccines and **harnessing the patient’s** own natural killer cells that can treat and prevent the recurrence of cancer. I went on to state that “we no longer just have to dream as this revolution of creating a cancer vaccine for N of 1 is at hand... and can be a lifelong legacy of this Administration.”

19. Shortly after our meeting on October 6, 2015, Vice President Biden announced on October 21, 2015 that he would not run for President of the United States, but would pursue his commitment to the cause of fighting cancer: He stated at the news conference: “**I believe we need a moonshot in this country to cure cancer.** It’s personal. But I know we can do this. The President and I have already been working hard on increasing funding for research and development -- because there are so many breakthroughs just on the horizon in science and medicine. The things that are just about to happen, we can make them real with an absolute national commitment to end cancer as we know it today. And I’m going to spend the next 15 months in this office pushing as hard as I can to accomplish this. Because I know there are Democrats and Republicans on the Hill who share our passion -- our passion to silence this deadly disease.”

20. Vice President Biden used the words from our white paper. Thus the assertion by Dr. DePinho and Dr. Lynda Chin that we usurped the government's moonshot is without basis. In fact, on November 1, 2015, *The New York Times* published an article on Vice President Biden's desire to create a "moonshot" to cure cancer stating that in describing this moonshot, Vice President Biden was adopting language from myself to describe his aspiration for cancer research. The New York Times article states as follows:

In describing this "moonshot," Mr. Biden was adopting language used by Dr. Soon-Shiong to describe his aspiration for cancer research. The two met for an hour in the White House just a few weeks ago, and Dr. Soon-Shiong gave the vice president a two-page outline of what he had in mind."

...The two-page paper Dr. Soon-Shiong gave Mr. Biden, titled in part "The Moonshot Program to Develop a Cancer Vaccine," advocates an expanded use of genome sequencing to understand individual cancers better and tailor treatments depending on their genetic characteristics. It forecasts the creation of patient-specific cancer vaccines that harness a person's own "natural killer cells" to treat and prevent the recurrence of cancer.

*...The paper, obtained from an associate of Mr. Biden's, proposes performing **full genomic sequencing of 100,000 cancer patients in the next 400 days** to create a vast database for supercomputer analysis, although no price tag is mentioned. "With 16 months to go, it is a perfect moment for the administration to deliver on this last mile, cementing this health care transformation into the fabric of health care," it says.*

Exhibit 15 is a copy of *The New York Times* article.

21. Vice President Biden wanted to learn more about the complexities of the immune system and the challenges that face rapid development of life-saving drugs, and requested further meetings to learn more of our program. On November 16th, 2015, Vice President Biden and his staff visited our campus in Los Angeles for a briefing and spent approximately 3 hours on our campus together with his staff and physician. Attached as Exhibit 16 are photos from Vice President Biden's visit to our Los Angeles campus on November 16, 2015. As can be seen from Exhibit 16, Page 9, the words in the center circle state "Overcoming Obstacles" "The QUILT

Coalition” “Moonshot for Cancer Vaccine” “The National Immunotherapy Initiative”. The assertion by Dr. DePinho that we usurped the government’s moonshot initiative which was announced two months later is without basis.

22. During the visit and briefing, I further informed the Vice President and his attending time of the obstacles that the country needed to overcome to make a **"quantum leap"** and execute a national collaboration to enable **what would normally take 10 years to be accomplished in 5 years**. Attached are copies of photographs of the white boards (which we have not erased), (Exhibit 16) showing my pictorial presentation to the Vice President in which we described out moonshot program. The language of **“ten years to five”** and **“Our MoonShot”** (Exhibit 16) is seen on the white board and this was the language which ultimately was published in the executive order (Exhibit 17) signed by President Obama on January 28, 2016, three months following Vice President Biden’s visit to our campus and the briefing on Cancer MoonShot 2020. An excerpt of the executive order is shown below:

The White House

Office of the Press Secretary

For Immediate Release

January 28, 2016

Memorandum -- White House Cancer Moonshot Task Force
January 28, 2016

**MEMORANDUM FOR THE HEADS OF EXECUTIVE
DEPARTMENTS AND AGENCIES**

SUBJECT: White House Cancer Moonshot Task Force
Cancer is a leading cause of death, and cancer incidence is expected to increase worldwide in the coming decades. But today, cancer research is on the cusp of major breakthroughs. It is of critical national importance that we accelerate progress towards prevention, treatment, and a cure -- **to double the rate of progress in the fight against cancer -- and put ourselves on a path to achieve**

in just 5 years research and treatment gains that otherwise might take a decade or more. . . .

(Exhibit 17.)

23. At the November 16, 2015 meeting in Los Angeles, I also shared with Vice President Biden that the most important element I believed that needed immediate attention, was to bring large pharmaceutical companies together to allow combinations of drugs and encourage the Food and Drug Administration (“FDA”) to allow novel combinations in next generation 21st century clinical trials and provided him and his team another briefing paper entitled (Exhibit 18) **“The Moon Shot: A National Immunotherapy Initiative for the Conquest of Cancer. The Cancer QUILT Coalition to Develop a Cancer Vaccine for N=1”** outlining this premise, which I provided to Vice President Biden during his visit of November 16, 2015. An excerpt is below:

The Moon Shot: A National Immunotherapy Initiative for the Conquest of Cancer

The Cancer QUILT Coalition to Develop a Cancer Vaccine for N=1

Background: In his seminal report on the “Cancer Crusade” Richard A. Rettig states, *“The large issue that divided people the most had to do with how scientific research be supported to improve the health of the American public most effectively and rapidly? On this key issue there was and is today an underlying, unresolved conflict”*. This issue stated in 1977 still remains today almost 40 years later.

There are unique times when events and advances in technologies converge to elicit a quantum leap in progress. That time is now for the rapid exploitation of immunotherapy for the benefit of millions of cancer patients. The cloning of the human genome has led to an enormous knowledge base as to how cancers are initiated and progress. Over the last several years scientists studying the cancer process have elucidated the fact that the vast majority of cancers arise and progress due to numerous mutations in cancer cells. Moreover, for the most part, each patient’s cancer is unique in terms of the nature and number of mutations. It has now been realized that this is one of the major reasons why many existing therapeutic regimens designed to target a single or even a few mutations have had limited success to date.

The Age of Immunotherapy in Cancer: The human immune system has evolved over the millennia to combat an enormous range of invasive entities, such as viruses and bacteria; indeed, the immense diversity of the healthy, intact human immune system is believed to be responsible for eliminating many potentially cancerous cells that arise during a lifetime. This is evidenced by studies that have shown that individuals with impaired immune systems, such as long term AIDS patients, will develop more cancers than individuals with a normal immune system. It is this unique diversity and the remarkable ability to survey and eliminate harmful entities that defines the human immune system, which can be exploited to combat the individual mutations reflected in so-called neo-antigens in tumor cells. The potential thus now exists to develop immunotherapies tailored to the unique tumor signature of individual patients.

(Exhibit 18).

24. I shared with Vice President Biden our multiple prior efforts dating from 2009 to accomplish this collaboration amongst clinicians, community oncologists, FDA, NCI, Payors, and Pharma and specifically described our “Breakthroughs in Medicine and Technology Summit,” held in Jackson Hole, Wyoming in August 2015 to hold a three-day summit to address these obstacles facing our nation and transforming cancer care. (Exhibit 19)

25. On November 16, 2015, I also provided Vice President Biden with a report titled “Advancing Medical Innovation for a Healthier America” that shows our ongoing efforts in this regard. Attached as Exhibit 20 is a copy of the report.

26. With these insights, Vice President Biden invited me to convene a meeting of representatives from pharma, payors, FDA, and the National Cancer Institute and medical oncologists both from academia and community. This four-hour meeting was held on December 1, 2015 at his residence on the Naval Observatory in Washington, D.C. It was hosted by Vice President Biden, and he asked me to chair and run the agenda of the meeting which I did. Attendees of the meeting included leadership from the FDA, NCI, Pharma, Payors, Community Oncologists, DoD, and Academic Centers: (Exhibit 21). The concept, execution and timelines

were spelled out in relative detail to each member in attendance in the form of a briefing booklet. A copy of the briefing booklet is attached as Exhibit 24 and photographs from the meeting are attached as Exhibit 25. The assertion made by Dr. DePinho and Dr. Lynda Chin that the FDA and NCI were not aware or associated with Cancer MoonShot 2020 is false and the baselessness of this statement is evidenced by the detailed notes that were taken during the discussions by the attendees at the meeting for the purpose of providing a detailed proceeding of the members.

- a. **Robert M. Califf, M.D.**, U.S. Food and Drug Administration (FDA),

Deputy Commissioner for Medical Products and Tobacco:

“There come moments in time where we ask why drugs tested do not work. I can remember that moment in cardiology 30 years ago where we took out things that did not work and kept things that did. We may be at that moment in time with cancer. The FDA is here to act as the ‘cattle prod’ to accelerate this moment when we are beginning to figure out how cancer works. The FDA is ready to be part of this historic coalition where we can provide clinical trial guidance for the combination of novel innovative agents brought into the coalition from the Cancer Moon Shot Program 2020 members. By adopting innovative and adaptive clinical trials, the QUILT coalition will shepherd in a period accelerated by innovation in cancer treatment.”

- b. **Janet Woodcock, M.D.**, U.S. Food and Drug Administration (FDA),

Director of the Center for Drug Evaluation and Research (CDER):

“Current clinical trials are organized around disease rather than immunology approaches. This traditional approach takes too long. You can only answer one question at a time and it may take you four years to answer one question about one drug and one tumor. It takes too long and doesn’t give you enough information. We need a large network to enroll a large number of patients. Almost all cancer patients are never enrolled in clinical trials. Almost all of them are never treated with investigational therapies. With regard to combinations, FDA issued guidance a number of years ago about investigational combinations. Development of Hepatitis C drugs is an example. My personal opinion: I believe we are approaching the science wrong. We have great basic science, we learn all this information but we don’t test it in the clinic in an

efficient manner. Anything we learn from a mouse or human pathology is a hypothesis, and often the hypothesis is wrong when we test it in people. In complexities such as we face today in cancer where we have next generation sequencing, when we wish to combine chemotherapy with immunotherapy, when we wish to explore multiple combinations, you're often asking five questions, not one. We need an engine that can turn around this knowledge rapidly and a process to help answer these questions effectively. An important issue is our need to involve the community, that's where the patients are. To date, trials have been centered around major medical centers and these trials are slow to accrue, since patients do not want to leave their community and doctors do not want to send them to remote centers. We need to build an infrastructure that will support these community doctors and allow them to participate and have their patients participate in these clinical trials without losing their patients and without having their patients to go away."

- c. **Peter W. Marks, M.D., Ph.D.**, U.S. Food and Drug Administration, Deputy Director for the Center for Biologics Evaluation and Research (CBER):

"Our goal is to enable important pathways for progress to get important therapies to patients. We will not be the impediment on the critical path at the FDA. Evidence generation needs to happen and we will work to streamline the process for vaccine development."

- d. **Jeffrey Schlom, Ph.D.**, Center for Cancer Research, National Cancer Institute, National Institutes of Health, Chief – Laboratory of Tumor Immunology and Biology:

"This coalition that has been brought together by Dr. Soon-Shiong to address cancer is one of the most comprehensive sets of talents, and is quite unique. I've seen it all but I've never seen anything quite like this in my years. I've been there at the original war on cancer during the Nixon Administration and saw the bureaucracy on how it played out.

The issue we face today in cancer care is a paradox. It is clear that immunotherapy can work in managing cancer but this approach is only working in about 20% of patients now. The problem we face

today is that there are about 2 dozen drugs in immunotherapy in the clinic right now and they are all being developed in silos by each individual company. This National Immunotherapy Coalition is designed to solve this problem. I'm extremely proud to be a part of this and have never seen a situation like this where we can get these trials done so rapidly. I've been revitalized, regenerated through this whole process."

- e. **James L. Gulley, M.D., Ph.D., FACP** Center for Cancer Research, National Cancer Institute, National Institutes of Health, Chief – Genitourinary Malignancies Branch:

"We are seeing a sea change on how we are treating patients with cancer with immunotherapy. We are seeing deep durable and rapid responses to these new immunotherapy agents that unfortunately are only in the minority of patients and in some cancers there's no responses at all. The best way to address these failures is to explore combination therapies and this National Immunotherapy Coalition is the vehicle to break down these silos and test these combinations rapidly. That's the way we are going to make progress. I am proud to be part of this important and historic immunotherapy initiative."

- f. **Col. Craig Shriver, MD, FACS (DOD)** - Walter Reed National Military Medical Center, Director, John P. Murtha Cancer Center:

"We validate big science through our clinical trials network. There are 1.2 million active duty military members, 9.3 million beneficiaries that receive military health care. That's a huge network. Just in our active duty force, we get a thousand active duty members a year that come down with cancer. If a thousand active duty members were still getting injured in Afghanistan or Iraq, we would not accept this. So it's the same thing with how militaries respond to infectious diseases, illnesses that affect the readiness of our active force. Cancer is that threat."

- g. **Ralph H. Hruban, M.D.**, Johns Hopkins University – Director, Sol Goldman Pancreatic Cancer Research Center:

"We are at a crossroads, a time of discovery that's transforming the ways we manage cancer. Johns Hopkins researchers and clinicians are working tirelessly to understand cancer better and to move treatments from bench to bedside so that patients can have a better

shot at beating the disease. It is my hope that the National Immunotherapy Coalition, and others like it, will advance the understanding of cancer, not by small steps, but instead by leaps and bounds.”

- h. **Mark C. Poznansky, M.D., Ph.D.,** Harvard Medical School; Massachusetts General Hospital Director, Vaccine & Immunotherapy Center:

“The time is now to create an accelerated path, and advance medical science forward to save lives and improve health worldwide. The National Immunotherapy Coalition clearly unites and leverages the resources and expertise of a diverse network of medical and business professionals to safely and rigorously accelerate the pace of discovery, development and actualization of cancer treatment. By accelerating the development of new safe and cost effective therapies combating cancer, we can bring them to those that are most in need faster and more cost effectively than current approaches.”

- i. **Stephen D. Nimer, M.D.,** University of Miami Health System – Director, Sylvester Comprehensive Cancer Center:

“Every day, the physicians and scientists within Sylvester Comprehensive Cancer Center’s site disease groups and multidisciplinary research programs, are working to make exciting breakthroughs that can transform the way cancer patients are diagnosed and treated. We look forward to working for the National Immunotherapy Coalition and developing the most innovative strategies to fight the most deadly forms of cancer.”

- j. **Azra Raza, M.D.,** Columbia University – Director, Myelodysplastic Syndrome Center:

“We are very pleased to have the opportunity to work with the National Immunotherapy Coalition and collaborate with a world-class team who share a commitment to reduce cancer incidence and to improve the quality of life of those affected by cancer. Being able to pool resources and agents, we will be able to make a significant leap in developing new immunotherapeutic and combinations that will most benefit patients with various cancer types and stages.”

- k. **Vivian S. Lee, M.D., Ph.D., M.B.A.**, University of Utah, SVP for Health Sciences; Dean, School of Medicine; CEO, University of Utah Health Care:

“There really is a no more fascinating or promising time to be in medicine. The National Immunotherapy Coalition is an amazing opportunity to discuss obstacles that may impede the successful moonshot for cancer and reach the goal of establishing an effective vaccine for this disease in 5 years instead of 20. The University of Utah is deeply committed to solving these dilemmas and I, for one, am heartened that we will help lead the way.”

- l. **Andrew M. Evens, DO, MSc, FACP**, Tufts University School of Medicine, Chief, Division of Hematology/Oncology; Director of Tufts Cancer Center:

“I am honored to join a group of world-renowned expert physicians, scientists and researchers who have a shared passion for fighting cancer. Cancer can affect every aspect of a person’s life — and the lives of their loved ones. That’s why we are dedicated to research that can bring new and innovative treatments to patients in less time.”

- m. **Paul Seligman, M.D., MPH**, Amgen, Chief of R&D Policy:

“At AMGEN, we are committed to using genomics and deep insights into biology to develop novel therapies for cancer. We are committed to the goals of collaborative research efforts in immuno-oncology and the development of innovative combination therapies. It is a time of unprecedented progress in our ability to understand how to harness the power of the immune system to treat tumors, and collaborative approaches represent a tremendous opportunity to combine the efforts of key stakeholders to accelerate progress.”

- n. **Patrick Vallance**, GlaxoSmithKline, President, Research & Development:

“Modernizing our thinking and taking a more open and collaborative approach to our research will allow us to make

greater progress in the development of new cancer therapies for patients. Everyone recognizes the future of effective cancer treatments lies in their combinations, but understanding what to combine and how best to use these isn't something companies can do alone. We could achieve much more together and I hope this National Immunotherapy Coalition will support the collection of data and sharing of information on existing treatments and those in clinical trials in a smart, collaborative way."

- o. **Mikael Dolsten, M.D., Ph.D.,** Pfizer, Inc., President, Worldwide

Research & Development:

"The challenge of cancer is far too great for any of us to tackle alone. It is our hope that the joining together of the health innovation ecosystem under the National Immunotherapy Coalition will further accelerate the development of game changing, combination immunotherapies for the benefit of cancer patients."

- p. **Frank R. Jones, Ph.D.,** Etubics Corporation, Chairman, President, and

CEO:

"At Etubics, we specialize in developing innovative immunotherapies and vaccines for a wide-range of resilient diseases including cancer, so it goes without saying that we are extremely excited about this new initiative. We recognize the value in an immune stimulation treatment approach and look forward to volunteering our agents for combination clinical trials that we anticipate will produce groundbreaking results."

- q. **Jim Huffman,** Bank of America, Senior Vice President, Head of US

Health and Wellness Benefits:

"Bank of America provides coverage for about 500,000 employees and their families and for the past five years has worked closely with NantHealth to explore innovative methods for improving health & wellness for their associates. We are doing our part to address an issue that affects the lives of our employees, our customers and clients, and the people in the communities we serve around the world. We are committed to providing the most advanced cancer care to our employees and the National Immunotherapy Coalition with its national footprint of oncologists practicing cutting edge medicine is a valuable resource we will now be able to offer to our 500,000 beneficiaries. Bank of America

has partnered with Dr. Soon-Shiong and his team over the past five years to bring advanced health and wellness to our associates and their families, and we are proud to be a part of this Cancer MoonShot 2020.”

- r. **Daniel J. Hilferty**, Independence Health Group, President and CEO:

“At Independence Blue Cross, we are proud to be the first major insurer offering reimbursement to our members for this next generation whole genome sequencing. We are committed to bringing state-of-the-art advances in oncology care to our members and making care accessible and affordable. Independence Blue Cross is committed to bringing state-of-the-art advances in oncology care. Although the science is still evolving, experts agree that immunotherapy is a game-changing approach that is expected to revolutionize the way we treat cancer in the future. We are proud to participate in the National Immunotherapy Coalition. We look forward to continued collaboration among this incredible team to develop the most innovative cancer fighting strategy in our lifetime.”

- s. **Paul M. Black**, Allscripts, CEO & Director:

“The National Immunotherapy Coalition is an exciting step towards a more efficient future in cancer treatment, partnering research and health information technology in an entirely new way. As a leader in healthcare information technology solutions, the EHR solution for the NIH and the NCI, we will play the critical role of connecting this newfound medical insight to the communities of healthcare professionals at the frontlines of care delivery. Combining the cutting edge research being done by NantWorks with the power of their Allscripts clinical information solutions will better harness the enormous volume of newly available data, allowing the dissemination of new discoveries much more rapidly to connected communities than has been possible in the past. We have seen already that when new research is presented in the clinicians' workflow efficiently and in a way that feels natural to them, it allows them to focus first and foremost on the well-being of all those dealing with cancer.”

- t. **John Chen**, Blackberry, CEO:

“At Blackberry, we understand the value that lies at the intersection of healthcare and technology, which is why we are constantly making advancements to reflect the ever-changing healthcare landscape. As we already power many of the tools that

clinicians rely on heavily, we are confident that our involvement in the National Immunotherapy Coalition will be an asset to the future of Cancer treatment. This unique collaboration is pioneering extraordinary solutions to cancer care and we are truly honored to be a part of it.”

(Exhibit 26).

27. At the conclusion of the meeting, the participants reached a consensus. We agreed that a formal announcement of “Cancer Moonshot 2020” would be made on January 11, 2016, at the nation’s largest health care conference sponsored by JP Morgan Chase in San Francisco, where CEOs of pharma, payers and health systems routinely gather every year. A press release was drafted and each member present at the Vice President’s meeting was offered the opportunity to be quoted in the announcement. The press release announced the launch of the “Cancer Moonshot 2020” program and the formation of the National Immunotherapy Coalition. A copy of a final version of the press release is attached as Exhibit 22.

28. Unbeknownst to us (and I believe even unbeknownst to Vice President Biden), the next day, on January 12, 2016, at the State of the Union address, President Obama announced that Vice President Biden would serve as the head of the government’s version of the moonshot program, which became known as the “National Cancer Moonshot Initiative.” Notably, President Obama announced the Government program *the day after we announced the Cancer Moonshot 2020 program*.

29. Background regarding the goals of these “moonshot” initiatives was provided in a June 2016 article in *Nature Biotechnology*. The article describes the various moonshot initiatives, including the National Cancer Moonshot Initiative, our Cancer Moonshot 2020 Program, and MD Anderson’s Moon Shots Program. Notably, when expressly asked whether there was any concern about confusion between the various moonshot programs, none of the representatives from any of the programs, including the University of Texas MD Anderson

Cancer Center, expressed any concern. A copy of the article is attached as Exhibit 23.

30. President Obama's Precision Medicine Initiative with Francis Collins is approaching the issue at an epidemiological level in healthy volunteers, while Cancer Moonshot 2020 is laser focused on patients faced with cancer in the real world, to drive immunotherapy and change the paradigm of care in the QUILT trials, with a timeline of accomplishment by 2020. Indeed, on September 17, 2015, Francis Collins, the Director of NIH provided a 108 page report entitled "The Precision Medicine Initiative Cohort Program – Building a Research Foundation for 21st Century Medicine" <https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf>. The executive summary states:

"In order to achieve the President's ambitious plan, the PMI Cohort Program (PMI-CP) will build a large research cohort of one million or more Americans that will provide the platform for expanding our knowledge of precision medicine approaches and that will benefit the nation for many years to come. In March of 2015, NIH Director Dr. Francis Collins formed the PMI Working Group of the Advisory Committee to the Director to develop a plan for creating and managing such a research cohort. To help carry out its charge, the Working Group engaged with stakeholders and members of the public through workshops and requests for information, focusing on issues related to the design and oversight of the cohort. Public engagement, as well as internal discussions among the Working Group, led to the vision for the design and utility of the cohort program outlined in this report. The report includes recommendations in **six areas critical to the development, implementation, and oversight of the PMI-CP: cohort assembly, participant engagement, data, biobanking, policy, and governance.** In addition to the recommendations, the Working Group outlined the potential utility and unique opportunities that could be addressed by the PMI cohort."

Notably, nowhere in the report is there evidence of the Cancer Moonshot program including: clinical trial development for immunotherapy, neoepitope vaccines in patients actively afflicted with cancer and integration with pharma and FDA for the development of novel-novel combinations – all key elements of Cancer MoonShot 2020. Instead, the PMI focuses on targeted therapy against disease-causing mutations. However, as we have pointed out in our briefing

document to the Vice President that the finding of tumor heterogeneity, renders targeted therapy alone incapable of curing the disease. In 2014, Gerlinger et al stated “...an illusion of clonal dominance when assessed by single biopsies. The presence of sub clonal driver events in solid tumours may provide an explanation for the inevitable acquisition of resistance to targeted therapeutics in advanced disease”. Thus again, there is scientific disagreement as to the approach to transform cancer care. Cancer MoonShot 2020 addresses this in a quantum method which we have term “Quantum-Oncotherapeutics” to recognize the ever-changing mutations in patients suffering from Cancer. The assertion by Dr. DePinho and Dr. Lynda Chin that Cancer MoonShot 2020 has usurped the Precision Medicine Initiative (PMI) initiated by President Obama and developed by Francis Collins per his working group, is baseless.

31. We were surprised and deeply disappointed by the unusual action of filing a lawsuit by the Board of Regent of the University of Texas, with no prior communication by the leadership to raise and address any concerns with our name despite substantial national press dating back to January 2016. In fact, I understand that the Board of Regents did not file any trademark applications claiming rights in the “moonshoot” name until it filed this lawsuit in October 2016. I have no idea why they would attempt to monopolize the common “moonshot” name.

32. The Board states in its lawsuit that the reason they want to stop us from using the Cancer Moonshot 2020 name is because they raised \$380 million dollars for their program. We made it very clear that Cancer MoonShot 2020 has not asked for one penny and this was again re-iterated during my participation in the Vice President’s Blue Ribbon Panel, a working group of the National Cancer Advisory Board. The Cancer Moonshot 2020 initiative is focused on changing the paradigm in the care of the patient. It is not a fundraising tool. We were surprised

and deeply disappointed by the unusual action of filing a lawsuit by the Board of Regent of the University of Texas, with no prior communication by the leadership to raise and address any concerns with our name despite substantial national press dating back to January 2016. In fact, I understand that the Board of Regents did not file any trademark applications claiming rights in the “moonshoot” name until it filed this lawsuit in October 2016. I have no idea why they would attempt to monopolize the common “moonshot” name.

33. I was also disappointed to learn that the Board of Regents filed a First Amended Complaint in which it devotes several pages to disparaging allegations regarding me and my career. While I understand that this declaration is not the time or the place to respond to these allegations, they are illustrative of the types of attacks that I have experienced when challenging the status quo and traditional practices in the industry. However, personal attacks have little to nothing to do with the fight against cancer, which we should all be focused on, and more to do with apparent obsession over a name and fundraising.

34. In my opinion, we cannot afford to be distracted by the pettiness of the words in the world of a patient facing a life-threatening disease such as cancer. It is not the name of a program that is important. Treating cancer is not about words, treating cancer is about action. When we launched Cancer MoonShot 2020, it was for a specific purpose -- to give the nation hope and change, bring together a coalition of stakeholders from various sectors, and ensure that by the year 2020 patients will receive combination immunotherapy without the ravages of high-dose chemotherapy. That has been, and continues to be, our singular purpose. We cannot be distracted by a war of words. What we are focused on is the interest of the patient. The trademark is of little significance: the cure is.

35. To the best of my knowledge, none of these activities relating to the adoption and

use of the Cancer Moonshot 2020 name involved the State of Texas.

Background on “moonshot” and the “Cancer 2020 Moonshot” Name

36. The word “moonshot” refers to a groundbreaking, ambitious program. It is inspired by President Kennedy’s aggressive and successful “moonshot” program to put an American on the moon within a decade of his 1961 speech. In my view, “moonshot” is not a name associated with a single program or a single entity or organization. It is a generic or descriptive term used by several organizations in a variety of fields.

37. In January 2016, Nant Holdings IP, LLC filed trademark applications for “Cancer MoonShot 2020,” “Cancer MoonShot 2020 Foundation,” and “Cancer Moonshot Network News.” The intent was not to stop others from using their own “moonshot” program names. Rather, I was only interested in protecting the very specific name of the program that we were involved in. To ensure freedom of use of the “moonshot” name by all, especially the world of community oncologists where 80 percent of cancer care is administered.

38. The CANCER MOONSHOT 2020 trademarks were allowed by United States Patent and Trademark Office.

Background on the Lack of Contacts with the State of Texas

39. I am a California citizen and resident. NantWorks is a Delaware limited liability company whose principal place of business is located in Culver City, California. Nant IP is a Delaware limited liability company whose principal place of business is located in Culver City, California. NantHealth is a Delaware corporation whose principal place of business is located in Culver City, California. However, NantHealth has an office in Dallas, Texas. In contrast, NantWorks and Nant IP do not engage in business in the State of Texas and have not engaged in business in the States of Texas at least for the past few years. I will refer to me, NantWorks and

Nant IP as the California Defendants.

40. The California Defendants are not citizens or residents of Texas.

41. The California Defendants do not maintain a place of business in Texas.

42. The California Defendants do not maintain offices, mailing addresses, or telephone numbers in Texas.

43. The California Defendants do not have any employees working in Texas.

44. The California Defendants are not licensed, registered, or authorized to do business in Texas.

45. The California Defendants are not required to maintain and do not maintain a registered agent for service of process in Texas.

46. The California Defendants have not filed any Articles of Organization or operating agreements in Texas.

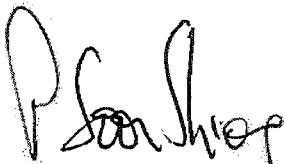
47. The California Defendants do not have any bank accounts located in Texas.

48. The California Defendants do not own any real property in Texas.

49. The California Defendants have not paid any income or property taxes to the State of Texas.

50. To my knowledge, the California Defendants have not used the CANCER MOONSHOT 2020 marks at issue in connection with any activity in the State of Texas. To my knowledge, anyone with knowledge of any such use would be residents of California and any documents relating to such use would be located in Culver City, California.

EXECUTED on this 16th day of December, 2016



Patrick Soon-Shiong, M.D.